II. Supplemental Information Disclosure Statement

Applicants will submit, in a separate paper, a supplemental information disclosure statement, which includes documents cited in a search report from the European Patent Office (EPO) for a corresponding patent application filed in the EPO.

III. Amendment of Claims 1, 5, 9, 10, 17, 19 and 23

Applicants have amended independent claims 1 and 17 to improve readability and to clarify that the recited dosage form is made by melt extrusion, which results in a dosage form having a central core that is a glassy matrix. Applicants have also amended claims 1 and 17 to clarify that the outer layer is impervious to water or bodily fluids. Applicants have deleted the term "Eudragit RS" from dependent claim 5, and have amended dependent claims 9 and 10 so that they are consistent with claims 1 and 17. Applicants have also amended dependent claims 19 and 23 to improve their readability. The specification, as filed, fully supports the changes to the claims, and therefore Applicants submit that the present amendment introduces no new matter. See, for example, the Application at page 3, line 10-14; page 9, lines 16-20 and 28-30; page 10, line 19-page 11, line 7.

IV Rejection of Claim 5 Under 35 U.S.C. § 112

The Office Action rejected claim 5 under 35 U.S.C. § 112, first paragraph, for containing the term "Eudragit RS." As indicated above, Applicants have deleted the term from claim 5.

V. Rejection of Claims Under 35 U.S.C. §§ 102(b), 103(a)

The Office Action rejected claims 1-3, 8, 9, 11, 12, 17, 19, 20-22 and 24 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,683,719 to Newton. The Office Action also rejected claims 1-10 and 12-16 under 35 U.S.C. § 103(a) as being unpatentable over Newton in view of U.S. Patent No. 4,572,833 to Pederson (claims 1-3, 5-10 and 12) and U.S. Patent Nos. 5,648,387 and 5,565,188 to Bisgaier et al. and Wong et al. (claims 1, 4 and 13-16). The Office Action also rejected claims 17, 18 and 23 under 35 U.S.C. § 103(a) as being unpatentable over Newton.

Applicants submit that Newton, Pederson, Bisgaier et al. and Wong et al., either alone or in combination, do not teach or suggest every limitation of independent claims 1 and 17, and therefore the cited references neither anticipate nor render obvious the claimed invention. Applicants therefore submit that claims 1 and 17, as well as claims 2-7, 9-12 and 18-24, which depend on claim 1 or claim 17, are patentable over the prior art of record. Applicants respectfully request withdrawal of the rejections.

Claims 1 and 17 recite a pharmaceutical dosage form and a method of making the pharmaceutical dosage form. In both claims, the pharmaceutical dosage form comprises a central core and a diffusion-limiting sleeve or outer layer. The central core has a pair of opposite end surfaces and a peripheral surface that extends between the opposite end surfaces. The diffusion-limiting sleeve, which is impervious to water or bodily fluids, surrounds the core's peripheral surface, but leaves the ends of the core exposed. As noted above, the pharmaceutical dosage form is formed by simultaneous melt extrusion of the core and sleeve. The dosage form is prepared by melt extrusion so that its core comprises a glassy matrix, which is structurally different than a dosage form prepared by a wet process or by a dry compressive process (e.g., tableting).

Applicants submit that none of the references teach or suggest a dosage form that is made by simultaneous melt extrusion of a central core and outer layer (sleeve), which results in the central core being a glassy matrix. Instead, Newton discloses controlled release compositions, which are prepared from a wet extrusion process (see e.g., col. 1, lines 21-25, col. 2, line 63-col. 3, line 15, and col. 5, lines 51-59). The resulting wet extrudate is then dried in an oven and coated in a fluidized bed coater (see e.g., col. 6, lines 2-14). Significantly, Newton's "core" is not glassy but is crystalline (see e.g., claim 1). Likewise, Pederson discloses solid dosage forms made by tableting (see e.g., col. 10, lines 40-44 and col. 12, lines 1-4), and neither Bisgaier et al. nor Wong et al. provide any details for preparing solid dosage forms.

VI. Conclusion

In view of the foregoing, Applicants respectfully submit that all pending claims are patentable over the prior art of record. If the Examiner has any questions, Applicants request that the Examiner telephone the undersigned.

Applicants believe that any fees associated with the filing of the present amendment have been identified in a transmittal that may accompany this paper. However, if any fees are required in connection with the filing of this paper, and such fees have not been identified in the accompanying transmittal, if any, please charge deposit account number 23-0455.

Respectfully submitted,

Date: October 25, 2002

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ATTACHMENTS:
Version With Markings To Show Changes Made

VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Amended) A pharmaceutical [Pharmaceutical] dosage form comprising a central core including a pharmaceutical agent in a controlled-release composition, said core having two exposed opposite end surfaces and a peripheral surface [at an outer edge of said core] extending between said two exposed opposite [opposed] end surfaces, said peripheral surface [edge] surrounded by a diffusion-limiting sleeve, [wherein] said sleeve [limits the] being substantially impervious to water or bodily fluids thereby limiting diffusion of fluids into said core, wherein said pharmaceutical dosage form is formed by simultaneous melt extrusion of said central core and said diffusion-limiting sleeve resulting in said central core being a glassy matrix.

5. (Amended) Pharmaceutical dosage form, as recited in Claim 1, wherein said diffusion-limiting sleeve [material] comprises at least one of ethyl cellulose and polymethacrylate [(Eudragit RS)].

9. (Amended) Pharmaceutical dosage form, as recited in Claim 1 [8], wherein said glassy matrix [material] comprises at least one material selected from the group consisting of polyethylene glycol, polyvinylalcohol, polymethacrylate, cellulose acetate phthalate, polyvinylpyrrolidone, hydroxypropylcellulose phthalate, hydroxypropylmethylcellulose, hydroxypropylmethylcellulose [hydroxyproplymethylcellulose] acetate succinate, hydroxypropylcellulose, hydroxypropylethylcellulose [hydroxypropyethylcellulose], and polysorbate 80.

10. (Amended) Pharmaceutical dosage form, as recited in Claim 9, wherein said glassy matrix [material] comprises polyvinylpyrrolidone and polyethylene glycol.

17. (Amended) A method [Method] of making a pharmaceutical dosage form comprising:

coextruding an indefinite length of [a] an at least partially melted central core and outer layer to form a co-extrudate having a longitudinal axis, said central core including a pharmaceutical agent disposed in a controlled-release composition, and said outer layer being substantially impervious to water or bodily fluids thereby limiting diffusion of fluids into said central core; [surrounded by a diffusion-limiting composition, and]

slicing said co-extrudate across the longitudinal axis thereof to form discrete pellets; and

cooling said co-extrudate so that said central core comprises a glassy matrix.

19. (Amended) Method of making a pharmaceutical dosage form, as recited in Claim 17, wherein said co-extrudate is sliced [across the longitudinal axis thereof in parallel,] perpendicular to said longitudinal axis.

23. (Amended) Method of making a pharmaceutical dosage form, as recited in Claim 17 [19], wherein said co-extrudate is sliced with a laser [across the longitudinal axis of the co-extrudate in parallel, perpendicular to said longitudinal axis].